Objectives: To report 30-day results from a prospective, nonrandomized, multicenter study that evaluated the safety and effectiveness of the Zenith TX2 Low Profile Endovascular Graft (TX2-LP, Cook Medical, Bloomington IN) for treatment of blunt thoracic aortic injuries.

Methods: The TX2-LP device is available in smaller graft diameters (starting at 18 mm) and lower profile delivery systems (starting at 16 Fr) than currently available thoracic endografts. The device (nitinol stents and polyester graft material) accommodates a tighter aortic curvature (radius of 20 mm) than the predicate TX2 Pro-Form. Primary endpoint was 30-day mortality.

Results: Between January 2013 and March 2014, 44 patients (40 men; mean age, 43 ± 19 years, range, 18-89 years) were treated at 17 US sites. The mean injury severity score was 30 ± 13 (range, 6-66). Technical success was achieved in 100% of patients, with 0% intraoperative mortality. Device access was entirely percutaneous in 17 patients (39%). Smaller size grafts (18-24 mm) were used in 15 patients (34%). The mean procedure time was 83 ± 46 minutes (range, 34-278 minutes), and mean blood loss was 109 ± 152 cc (range, 0-1000 cc). The 30-day mortality rate was 2%: one patient died 24 days postprocedure from respiratory failure related to associated injuries and not to the device or procedure as adjudicated by an independent clinical events committee (CEC). One patient experienced incomplete quadriplegia on the day of the procedure (CEC adjudication pending) and one patient experienced a stroke 7 days postprocedure (cause undetermined by the CEC). One patient underwent reintervention for a site-reported proximal type I endoleak (core lab reported unknown endoleak type) at 30 days postprocedure. There have been no conversions to open surgical repair.

Conclusions: Short-term results indicate that the TX2-LP device appears safe and effective for the treatment of blunt thoracic aortic injuries. Further enrollment and follow-up are ongoing.

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L6.

Five-Year Results of the United States Multicenter Prospective Study Evaluating the Zenith® Fenestrated Endovascular Graft for Treatment of Juxtarenal Abdominal Aortic Aneurysms

Gustavo S. Oderich[1], Roy K. Greenberg[2]†, Mark Farber[3], Sean Lyden[2], Luis Sanchez[4], Ron Fairman[5], Feiyi Jia[6], Priya Bharadwaj[6], on behalf of the Zenith Fenestrated Study Investigators. [1]Mayo Clinic, Rochester, Minn; [2]Cleveland Clinic, Cleveland, Ohio; [3]University of North Carolina, Chapel Hill, NC; [4]Washington University, St. Louis, Mo; [5]University of Pennsylvania, Philadelphia, Pa; [6]Med Institute Inc, West Lafayette, Ind†In memoriam

Objectives: This study reports results of a prospective, multicenter trial designed to evaluate the safety and effectiveness of the Zenith® Fenestrated AAA Endovascular Graft (ZFEN, Cook Medical, Bloomington IN) for treatment of juxtarenal abdominal aortic aneurysms (AAAs).

Methods: Sixty-seven patients with juxtarenal AAAs were prospectively enrolled in 14 U.S. centers (2005-2012). Custom-made fenestrated stent-grafts were designed with up to three fenestrations based on analysis of computed tomography (CT) datasets. Renal alignment was performed using balloon-expandable stents. Follow up included clinical examination, laboratory studies, duplex ultrasound, abdominal X-rays and CT imaging at hospital discharge, 1, 6, 12 months, and yearly thereafter up to 5 years.

Results: here were 54 male and 13 female patients with a mean age of 74±8 years old enrolled. Mean aneurysm diameter was 60 ± 10 mm. A total of 178 visceral arteries required incorporation with small fenestrations in 118, scallops in 51 and large fenestrations in 9. Of these, all 118 small fenestrations (100%), 8 of the scallops (16%), and 1 of the large fenestrations (11%) were aligned by stents. Technical success was 100%. There was one postoperative death within 30 days (1.5%). Mean length of hospital stay was 3 ± 2 days. There were no type I or III endoleaks, aneurysm ruptures or conversions noted during a mean follow up of 37 ± 17 months (3-65 months). Two patients (3%) had migration >5 mm with no endoleak due to cranial progression of aortic disease. Of a total of 129 renal arteries targeted by a fenestration, there were 4 (3%) renal artery occlusions and 10 (8%) stenoses. Fifteen patients (22%) required secondary interventions for renal artery stenosis/occlusion in 11 patients, type II endoleak in three and indeterminate endoleak in one. At 5 years, patient survival was 91% ± 4%, freedom from major adverse events was 79% ± 6%, primary and secondary patency of targeted renal arteries was 81±5% and 97% ± 2%, freedom from renal function deterioration was 91±5%, and freedom from secondary interventions was 63% ± 9%.

Conclusions: This prospective study demonstrates that endovascular repair of juxtarenal AAAs using ZFEN is safe, effective and durable. Mortality and morbidity are low in properly selected patients treated in centers with experience in these procedures.

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†In memoriam